JUL 1 0 2000

K002625

510(k) Notification for PRONOVA Nonabsorbable Suture, USP

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: PRONOVA Nonabsorbable suture, USP

PREDICATE DEVICES NAME: SURGILENE and PROLENE sutures

510(k) SUMMARY

Device Description

PRONOVA suture, clear or pigmented, is a sterile, monofilament synthetic nonabsorbable surgical suture prepared from blends of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

Intended Use

PRONOVA suture is intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

PRONOVA suture has the same intended use as the predicate devices SURGILENE and PROLENE sutures.

K990625

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement

PRONOVA suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

Technological Characteristics

The new device has similar technological characteristics as the predicate devices. Like the predicate devices it is sterile, it is a monofilament nonabsorbable that conforms to the USP Monograph for nonabsorbable sutures.

Performance Data

Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP Monograph for nonabsorbable surgical sutures. Additionally, preclinical animal testing was provided showing that the device performed as intended.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFT 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory R. Jones
Director, Regulatory Affairs
ETHICON, Inc.
Route 22 West
Somerville, New Jersey 08876-0151

Date

May 15, 2000

K004625

JUL 1 0 2000

510(k) Notification for PRONOVA Nonabsorbable Suture, USP

SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(k) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

NEW DEVICE NAME: PRONOVA Nonabsorbable suture, USP

PREDICATE DEVICES NAME: SURGILENE and PROLENE sutures

510(k) SUMMARY

Device Description

PRONOVA suture, clear or pigmented, is a sterile, monofilament synthetic nonabsorbable surgical suture prepared from blends of poly(vinylidene fluoride) and poly(vinylidene fluoride-co-hexafluoropropylene).

Intended Use

PRONOVA suture is intended for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

PRONOVA suture has the same intended use as the predicate devices SURGILENE and PROLENE sutures.

K990625

SUMMARY OF SAFETY AND EFFECTIVENESS, Continued

510(k) SUMMARY, Continued

Indications Statement

PRONOVA suture is indicated for use in general soft tissue approximation and/or ligation including use in cardiovascular, ophthalmic, and neurological procedures.

Technological Characteristics

The new device has similar technological characteristics as the predicate devices. Like the predicate devices it is sterile, it is a monofilament nonabsorbable that conforms to the USP Monograph for nonabsorbable sutures.

Performance Data

Non-clinical laboratory testing was performed demonstrating that the device conformed to the USP Monograph for nonabsorbable surgical sutures. Additionally, preclinical animal testing was provided showing that the device performed as intended.

Conclusions

Based on the 510(k) summaries and 510(k) statements (21 CFT 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Devices under the Federal Food, Drug, and Cosmetic Act.

Contact

Gregory R. Jones
Director, Regulatory Affairs
ETHICON, Inc.
Route 22 West
Somerville, New Jersey 08876-0151

Date

May 15, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 1 2001

Mr. Peter Cecchini
Manager, Regulatory Affairs
Ethicon, Inc.
P.O. Box 151
Somerville, New Jersey 08876-0151

Re: K001625
Trade Name: PRONOVA Nonabsorbable Suture
Regulatory Class: II
Product Code: GAW
Dated: May 15, 2000
Received: May 17, 2000

Dear Mr. Cecchini:

This letter corrects our substantially equivalent letter of July 10, 2000 that includes limitations placed on the marketing of your suture. Your device is no longer subject to the previous limitations placed on the marketing of your suture and is substantially equivalent in accordance with the information below.

We reviewed your Section 510(k) notification of intent to market the device referenced above and determined that the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General (QS) regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under

This letter will allow you to continue marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number (if known): K001625

Device Name: PRONOVA Nonabsorbable Suture, USP

Indications for Use: PRONOVA Suture is indicated for use in general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

Donna R. Lochner
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K001625

(Optional Format 1-2-9G)